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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,785	12/20/2000	William J. Curatolo	PC10755AJTJ	8464

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1615	15

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/742,785	Applicant(s) CURATOLO ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-155* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims withdrawn from consideration are 3-11,19-24,32-40,48-53,60-68,76-81,88-91,96-101,108-111,116-121,128-131,136-141 and 148-150.

Continuation of Disposition of Claims: Claims rejected are 1,2,12-18,25-31,41-47,54-59,69-75,82-87,92-95,102-107,112-115,122-127,132-135,142-147 and 151-155.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time filed 01/21/03 and 08/08/03; request for continued examination under 37 CFR 1.114 and amendment B filed 01/21/03; prior art filed 01/27/03 and response to election requirement filed 08/08/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 01/21/03 has been entered.

Election Requirement

Applicants elected claims 1, 2, 12-18, 25-31, 41-47, 54-59, 69-75, 82-87, 92-95, 102-107, 112-115, 122-127, 132-135, 142-147 and 151-155 that are readable on crystalline highly soluble salt form and ionizable cellulosic polymer. Examiner considers the election to be have done without prejudice.

Specification

1. The disclosure is objected to because of the following informalities: Page 3, line 20 does not have the US Patent number listed.

Appropriate correction is required.

Applicants in the response to the election requirement state that the US-Patent number that may correspond to the PCT application will be inserted when the patent issues. However,

this objection will continue to be made and applicants have the option to amend the specification to correct the statement in context and in agreement with the present state of the application. It may be sufficient to refer to the PCT application now and refer to any patents issuing from the PCT application if the same becomes necessary when the current application is passed to issue; a correction is respectfully required until such a time.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 146, 147, 151-155 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 146 and 155 are vague and confusing because it is not clear how the aqueous solution is formed in a use environment such as in vitro and in vivo.

4. Claims 103, 104, 123 and 124 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 103 and 123 recite the limitation "said drug is administered separately from said concentration enhancing polymer" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim because claim 86 co-administers the drug and the concentration-enhancing polymer.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 12-18, 25-31, 41-47, 54-59, 69-75, 82-87, 92-95, 102, 105-107, 112-115, 122, 125-127, 132-135 and 142-145 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US 5,496,561).

Okada discloses a controlled release pharmaceutical composition comprising crystalline form of a drug (column 3, line 32); polymer such as hydroxypropylmethylcellulose acetate succinate, hydoxypropylmethylcellulose phthalate, cellulose acetate phthalate and carboxymethylethyl cellulose (column 3, lines 36-39, column 4, lines 20-25); plasticizers such as triethyl citrate, triacetin, polyethylene glycol, castor oil, polysorbitan monooleate, glycerine fatty acid ester (column 5, lines 5-8).

The instant application claims a composition that comprises a drug in a pharmaceutically acceptable solubility-improved form and a concentration-enhancing polymer is a salt and several examples of drugs that are suitable in the instant invention are listed in the specification (page 30, line 31 to page 31 line 5, page 35, line 13 to page 36 line 26 and page 26, line 30 to page 29 line 18). In the instant application, the recitation that the composition achieves a maximum equilibrium concentration of at least 1.25 fold of a drug ... is a property of the drug composition

and property of a composition is not separable from the composition; and thus the composition of the prior art would inherently achieve said equilibrium concentration relative to the drug.

Instant claims 25-28, 30, 54-57 and 82 recite the property of the composition and the teaching of Okada meets the limitations of said claims; diclofenac, which is one of the drugs disclosed in Okada has analgesic, anti-inflammatory and antipyretic activities; and thus Okada meets the limitation of instant claim 29. The method of the instant claims administers the drug and the concentration-enhancing polymer and the prior art teaches administering the composition to a patient/subject in need thereof.

8. Claims 1, 2, 12-14, 16, 25-31, 41-43, 45, 54-59, 69-71, 73, 82-87, 93, 102, 105-107, 113, 122, 125-127, 133 and 142-145 rejected under 35 U.S.C. 102(b) as being anticipated by Piergiorgio et al. (US 4,880,623).

Piergiorgio teaches a composition comprising nifedipine (an anti-hypertensive), polyethylene glycol, hydroxypropylmethyl cellulose and other excipients (abstract and example 2). Piergiorgio teaches that the bioavailability of the drug in the above composition is highly increased. The polymers of the prior art fall within the scope of the polymers that applicants regard as "concentration enhancing." The method of the prior art administers the drug with the concentration-enhancing polymer and the prior art meets the limitation because the prior art administers the composition to a subject in need thereof.

Applicants' traversal of the rejection centers on the argument that Piergiorgio's polymers are not used to enhance concentration but rather are used as "a matrix which adds additional sustained release characteristics to a formulation which is already sustained release." Thus,

applicants argue, one skilled in the art would not use the polymers of the prior art to enhance bioavailability or concentration of drugs.

Applicants' arguments filed 04/15/02 have been fully considered but they are not persuasive.

The claims are directed to a composition comprising a drug and a polymer that applicants have labeled "concentration enhancing." The polymers of the prior art fall within the scope of the polymers that applicants regard as "concentration enhancing." Applicants provided no data showing that the polymers disclosed and taught by Piergiorgio would not enhance drug concentration.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 15, 17, 18, 44, 46, 47, 72, 74, 75, 92, 94, 95, 112, 114, 115, 132, 134 and 135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piergiorgio et al. (US 4,880,623).

Piergiorgio discloses the composition and method of the instant claims except that Piergiorgio does not teach the polymer recited in the above claims. However, one concentration- enhancing polymer can substitute for another concentration enhancing polymer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the drug composition of Piergiorgio et al. (US 4,880,623). One having ordinary skill in the art would have been motivated to substitute one concentration-enhancing polymer with another with the expectation of enhancing the concentration of the drug in the use environment.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1, 16-18, 25-28 and 30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6, 7, 10 and 12-14, of copending Application No. 10/176462. Although the conflicting claims are not identical, they are not patentably distinct from each other because the solubility-improved drug in the co-pending application as recited in lines 22-25 is encompassed in the broad solubility improved drug of the examined application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Observation: Applicants have used the term "cellulosic" in a number of claims and the term may be replace with cellulose to overcome 35 USC 112, second paragraph issue since the cellulose materials encompassed by the "cellulosic" is not ascertained.

13. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600